UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

RANDALL HIX, *et al.,*

Plaintiffs,

v.

ZIMMER BIOMET HOLDINGS, INC, *et al*.,

Defendants.

Case No. 3:18-cv-00437-RCJ-WGC

ORDER

In 2010, Randall Hix had an artificial hip replacement using a Biomet M2a Magnum implant. Hix and his wife, Liana Hix, brought this suit against Defendants Zimmer Biomet Holdings, Inc., Biomet, Inc., Biomet Orthopedics, LLC, and Biomet U.S. Reconstruction, LLC, (collectively "Biomet") alleging the artificial hip device was defective. (Amended Complaint, ECF No. 201). Presently before the Court is Biomet's Motion to Exclude Case-Specific Expert Francis H. Gannon, M.D. (ECF No. 271). Hix opposes the motion. (ECF No. 280). The Court will grant the motion in part and deny it in part.

I. PROCEDURAL HISTORY

On October 2, 2012, the Judicial Panel on Multidistrict Litigation transferred the first actions regarding Biomet M2a Magnum hip implants to the Northern District of Indiana as the Biomet M2a Magnum Hip Implants Products Liability multi-district litigation, MDL Case No. 3-12-md-2391. In February 2013, the MDL court entered an order allowing parties to file new actions directly into the MDL action. In March 2014, Hix initiated this action by filing a complaint in the Biomet M2a

Magnum MDL. Following consolidated pre-trial proceedings primarily directed to common-issue discovery and to some case-specific discovery, the MDL court transferred this matter to the District of Nevada in September 2018.

II. BACKGROUND

On July 12, 2010, Hix (then 36 years old) had a total hip arthroplasty (THA, i.e., joint replacement) performed by Dr. Richard Mullins. Dr. Mullins implanted the Biomet M2a Magnum metal-on-metal (MoM) artificial hip device.

Prior to the THA procedure, Hix had surgery in 1997 on his left hip due to a Slipped Capital Femoral Epiphysis when he was 13 years old.

In 2008, Hix began experiencing pain in his left hip that worsened over time. In March 2010, Hix was arthroscopically treated for left hip femoroacetabular impingement. When the procedure did not resolve Hix's pain, he was referred to Dr. Mullins, who recommended a total left hip replacement. Hix and Dr. Mullins met with a Biomet sales representative who demonstrated Biomet's sample hip prosthetics. Dr. Mullins thought that a metal-on-metal device would provide Hix a better quality of life – and would last longer – than a metal-on-polyethylene device. Hix decided to have the M2a Magnum MoM device implanted.

Following the THA procedure, Hix began again experiencing pain in his left hip in March 2012. He saw Dr. Suzanne Zsikla, who referred Hix to Dr. Richard Blakey, an orthopedic surgeon. Hix saw Dr. Blakey in August 2012. A radiograph was taken, showing the MoM implant with reactive bone at the end of the stem. A presumptive diagnosis of metallosis[1] was made.

A bone scan performed on September 5, 2012, indicated Hix's hip was normal and did not indicate an abnormal uptake. On September 11, 2012, Dr. Blakey indicated he was fairly certain

[1] In his deposition, Hix's treating physician, Dr. Blakey, described metallosis as an inflammatory reaction to the wear product of an MoM device.

Hix did not have an infection and recommended a revision of the Biomet M2a Magnum MoM hip device.

Dr. Blakey performed the revision surgery on Hix's left hip on October 31, 2012. Dr. Blakey removed the Biomet acetabular cup and replaced it with a Zimmer metal-on-polyethylene constrained hip construct. He also removed damaged tissue and implanted a constrained liner to reduce the chance of dislocation or subluxation. Dr. Tony Yang examined the removed tissues for pathology and noted chronic inflammation, reactive hyperplasia, and pigmented macrophages containing a grayish pigment consistent with foreign material. Dr. Blakey's post-operative diagnosis noted painful left metal-on-metal total hip secondary to metallosis.

Two weeks after this surgery, Hix had an MRI of his lumbar spine, which showed an L5-S1 right-sided paracentral disc protrusion causing mild stenosis of the right neural foramina.

On January 10, 2013, Hix was seen by Dr. Blakey as Hix had "developed some cellulitis about the left hip wound." Dr. Blakey informed Hix that he might need to aspirate the hip. This procedure was performed on January 24, but produced "little fluid, if any." Cultures on the fluid were negative for infection. Hix was continuing to have pain when he had an office visit with Dr. Blakey in June 2013. Dr. Blakey "talked to [Hix] about the fact that sometimes the metallosis reaction comes back even though we have revised the hip." Dr. Blakey performed another left-hip aspiration in August 2013 and gave Hix a steroid injection.

Hix had a follow-up visit a week later. Dr. Blakey recorded in his notes: "I suspect that he is having continued inflammation, possibly from the metallosis." Following an office visit two weeks later, Dr. Blakey noted there was not much else he could do for Hix's pain.

Hix continued to have pain through 2014. In November 2014, Hix saw Dr. Martin Arraiz, who noted radiculitis (pain radiating along a nerve resulting from inflammation at the root of the

nerve connecting to the spine) in the lower left extremity. Hix received an epidural injection in December 2014.

Hix saw Dr. Blakey in January 2015. Dr. Blakey noted Hix "is actually getting better with respect to his left hip. He is still having pain." Following a July 2015 office visit, Dr. Blakey noted "Hix has had increasing pain in his left hip revision last month."

On October 21, 2017, Hix went to the emergency room the day following "kicking an object . . . with his left leg" that resulted in "sudden onset pain left hip." The emergency doctor noted a final impression of "[p]ain of left hip joint" and "[d]islocation of left hip."

Two days later, Dr. Chad Watts performed a revision surgery on Hix's left hip for "failed constrained liner with dislocation of left total hip." Dr. Watts removed the cup with constrained liner and replaced it with a "62 Biomet OsseoTi shell with dual mobility liner" and "2B +6 revision ceramic head with a titanium sleeve." Dr. Watts notes indicate that Hix "was very scarred in and had a pretty stiff hip. There was some metal staining from his prior metallosis, but overall the muscle and tissues were in reasonable shape." He further noted the "constrained liner was broken – there had clearly been chronic impingement which led to failure."

Four weeks after the surgery, Hix visited the emergency room with "pain to the surgical site, redness, and drainage around surgical incision associated with fever (102.0 deg F) and chills." Hix underwent surgery the following day to open the surgical wound for "drainage with debridement and placement of wound VAC." Two days later, Dr. Robert Crouse performed another surgery. As Hix had "an obvious deep infection," Dr. Crouse removed the artificial hip devices, removed infected material for biopsy and culture, and performed a femoral osteotomy. Dr. Crouse further placed an antibiotic impregnated cement spacer in the acetabulum, the location of the infection. The material removed for culture showed growth for Staphylococcus lugdunensis, with 1 of 3 cultures showing

growth for Methicillin-Resistant Staphylococcus aureus. Hix remained on IV antibiotics for six weeks.

On February 8, 2018, Dr. Watts implanted an artificial hip consisting of a Stryker Restoration cup and stem with a ceramic head and cable.

Hix had an office visit with Dr. Ali Nairizi in June 2018 for pain management. Over the following year, Hix underwent a femoral nerve block, lumbar sympathetic nerve block, and SI joint injections with corticosteroids for pain.

In September 2019, Dr. Denis Patterson implanted a temporary dorsal root ganglion spinal cord stimulator for pain management and implanted a permanent stimulator the next month.

In November, Hix had an office visit with Dr. Watts, reporting a significant increase in pain and redness and swelling around the left hip. Dr. Watts recorded the impression of "[l]ikely infected left hip replacement." Dr. Watts aspirated the left hip. A culture of the withdrawn material indicated a streptococcus viridans infection. Hix underwent surgery on his left hip the following day, with Dr. Watts performing a tissue debridement and irrigation, and exchanging the MDM liner, the ceramic head and MDM head. On December 1, 2019, Dr. Watts performed another debridement and irrigation of the hip. Hix was hospitalized for the infected left hip from November 22, through December 11, 2019.

In May 2020, Dr. Patterson exchanged the implantable power generator for the nerve stimulator.

III. LEGAL STANDARDS

A. Admissibility of Expert Testimony

Federal Rule of Evidence 702 governs the admission of expert testimony and provides that if a witness is qualified as an expert by knowledge, skill, experience, training, or education, the witness can provide opinion testimony so long as:

> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
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> (b) the testimony is based on sufficient facts or data;
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> (c) the testimony is the product of reliable principles and methods; and
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> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

The task of the trial court is to "assure that the expert testimony 'both rests on a reliable foundation and is relevant to the task at hand.'" *Primiano v. Cook,* 598 F.3d 558, 564 (9th Cir. 2010) *quoting Daubert v. Merrell Dow Pharms., Inc*., 509 U.S. 579, 597 (1993). This task applies to all expert testimony governed by Rule 702. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147-148 (1999). Rule 702 "is premised on an assumption that the expert's opinion will have a reliable basis in the knowledge and experience of [the relevant] discipline." *Daubert*, 509 U.S. at 592. The party offering the expert witness "has the burden of establishing that the pertinent admissibility requirements are met by a preponderance of the evidence." Fed. R. Evid. 702 Advisory Committee Notes.

"[M]any factors will bear on the inquiry." *Daubert*, 509 U.S. at 593. In considering the admissibility of scientific expert testimony, the Supreme Court generally noted four factors while acknowledging that it was not setting "out a definitive checklist or test." *Id.* As summarized by the Ninth Circuit, a court may consider: "1) whether the theory can be or has been tested; (2) whether the theory has been subjected to peer review and publication; (3) the known or potential rate of error and the existence of standards controlling a technique's operation; and (4) whether or not the theory is generally accepted." *United States v.Hankey*, 203 F.3d 1160, 1167 (9th Cir. 2000). However, these factors "may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony." *Kumho*, 526 U.S. at 150.

Ultimately, the court must "make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Id.* at 152.

IV. DISCUSSION

In his case-specific report, Dr. Gannon found that "[t]he medical records, laboratory results, diagnostic findings and deposition testimony in Mr. Hix's chart are consistent with the findings of an adverse reaction to metal-on-metal debris resulting from the July 12, 2010 left metal-on-metal hip implant." Dr. Gannon further found: "This adverse reaction caused Mr. Hix's first revision surgery on October 31, 2012." Biomet does not seek to exclude these expert opinions.[2]

Dr. Gannon further opines that "[t]his adverse reaction to metal-on-metal debris also resulted in long term muscle/tissue damage, which was consistent with this patient's continued post-revision left hip pain leading up to Mr. Hix's dislocation and second revision surgery in October 2017." Biomet argues that Dr. Gannon cannot offer this as an expert opinion because it is "premised solely on his general opinions as a physician, thus making it impracticable for this Court (or Biomet) to assess his principles and methodology."

In his deposition, Dr. Gannon further stated that he had formed an opinion "that necrotic tissue when it's retained in the body as a result of the metal-on-metal wear debris is – any necrotic tissue is a breeding ground for bacterial infection. So it is . . . not surprising at all that this patient has had multiple infections." Dr. Gannon indicated that he had discussed this in the case-specific report in his statement that "[t]his adverse reaction to metal-on-metal debris also resulted in long

[2] The Court notes that Biomet has captioned its motion as generally seeking to exclude Dr. Gannon as a case-specific expert. Further, Biomet's introductory sentences also indicate that it is seeking to generally exclude the opinions of Dr. Gannon. Biomet's arguments, however, are directed only at the two specific opinions regarding causation of the October 2017 revision surgery and the November 2017 infection.

term muscle/tissue damage," and explained "that is the result of tissue necrosis, and that would be ongoing as long as the metal debris was still resident in the body." Biomet argues that Dr. Gannon cannot offer an opinion that the debris from the metal-on-metal hip implant caused the November 2017 infection both because Dr. Gannon relied solely on his personal experience and because these opinions were not included in his case-specific report and supplemental report.

Hix argues that Dr. Gannon did rely on appropriate methodologies to reach his conclusion, noting that personal knowledge and experience are important factors in the field of medicine.

Biomet's arguments that Dr. Gannon cannot offer any causation opinion of Hix's medical course after 2012 appears to rest solely on its arguments that Dr. Gannon did not rely on pathology slides to form this opinion and that he did not adequately perform a differential diagnosis. The record, however, offers a sufficient basis to conclude that Dr. Gannon could form both an expert opinion that "an adverse reaction to metal-on-metal debris resulting from the July 12, 2010 left metal-on-metal hip implant" which "caused Mr. Hix's first revision surgery on October 31, 2012," as well as an expert opinion that this caused "long term muscle/tissue damage" that was consistent with Hix's medical course after 2012. The issues Biomet raises to the Court can be appropriately addressed in cross examination that will allow the jury to consider the weight to be afforded Dr. Gannon's expert opinions. The Court will not exclude these opinions.

The Court agrees, however, that Dr. Gannon did not adequately disclose, in his case-specific reports, his opinion regarding the cause of the infections Hix suffered after October 2017. The Court will exclude those opinions.

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CONCLUSION

IT IS HEREBY ORDERED that the Motion in Limine to Exclude Plaintiff's Case-Specific Expert Francis H. Gannon, M.D. brought by Zimmer Biomet Holdings, Inc., Biomet, Inc., Biomet Orthopedics, LLC, and Biomet U.S. Reconstruction, LLC. (ECF No. 271) is GRANTED in part and DENIED in part as set forth above.

IT IS SO ORDERED.

Dated: March 29, 2022

ROBERT C. JONES
United States District Judge